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1171/39247/91 # 5

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

In re application of)
)
SALMON and PAYTON)
)
Serial No.: 09/802,251)
)
Filed: March 8, 2001)
)
For: Radiant Warmer)

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Tiffany E. Sexton
Tiffany E. Sexton

TRANSMITTAL OF CERTIFIED COPY
REGARDING CONVENTION CLAIM UNDER 35 U.S.C. §119

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

The above-noted patent application was filed claiming priority with respect to New Zealand Application No. 503265, dated March 8, 2000. In completion of Applicant's claim for priority under 35 USC 119, please find enclosed herewith a Certified Copy of the aforementioned New Zealand Application.

It is believed that this completes Applicant's claim for priority and acknowledgment of receipt of this priority document is requested.

Respectfully submitted,

Dated: July 5, 2001

By _____

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Intellectual Property Office of New Zealand

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 8 March 2000 with an application for Letters Patent number 503265 made by FISHER & PAYKEL LIMITED.

Dated 20 March 2001.

Neville Harris
Commissioner of Patents

COMMISSIONER OF PATENTS TRADE MARKS & DESIGNS
NEW ZEALAND

503265

NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"AN IMPROVED INCUBATOR"

We, FISHER & PAYKEL LIMITED, a company duly incorporated under the laws of New Zealand of 78 Springs Road, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

AN IMPROVED INCUBATOR

The present invention relates to the use of a radiant incubator for infant care.

Neonates, particularly prematurely born infants, require special care for a period after being born. In particular, they require environmental control including tight control over the environmental temperature and also the quality of the air by which they are surrounded. In such circumstances it is typical for the neonate to by treated in an incubator using convection heating or other methods to maintain the ambient air temperature.

There are a number of other methods known in the art for regulating the temperature of the infant. For example, WO 98/48757 discloses the construction of a radiant heating element which can be used in infant radiant warmers of varying type. US 5,817,002 relates to a combination incubator with radiant warmer which is operable in a number of different modes and includes convective heat transfer and heated air curtains in addition to the radiant heating head. US 5,285,519 describes a transparent film radiant heater provided in the form of an incubator hood. US 5,498,229 relates to an infant radiant warmer incorporating transparent film radiant heating panels. US 4,972,842 concentrates on the monitoring of physiological parameters associated with the ventilation of infants during assisted ventilation, as an adjunct it refers to providing a constant temperature environment for the infant using a combination of convective and radiant heating. US 4,712,263 relates to the provision of a bubble-like self-supporting thermal barrier for use with neonatal infants on open radiant warmer beds or in convection warmed infant incubators. EP 619995 appears to show a radiant warmer in which the radiant heating source is divided into two blocks which are spaced apart in the longitudinal direction of the table to which the heating unit is attached. GB 1546734 includes side panels which are raised to "at or about blood heat". It is unlikely that actual radiant heating of the infant is anticipated, rather than the temperature of the convected air is not affected.

To some extent, at least, the above examples will be ineffective at accurately regulating the temperature of the infant. Further, in many cases the method used will be inefficient. In the incubatory examples when access is required the infant will often go unheated while being attended to.

This is an object of the present invention to provide a radiant incubator which goes some way toward overcoming the above-mentioned disadvantages or which will at least provide the health care industry with a useful choice.

Accordingly, in a first aspect the present invention may be broadly said to consist in an apparatus for heating an infant comprising:

a surface adapted to support said infant,

cover means adapted to attach to and extend over said surface, and

at least one radiant heating means associated with either said cover means or said surface, and

control means for energising said at least one radiant heating means such that in use the skin temperature of said infant is regulated within a predetermined range.

Preferably said apparatus further comprises temperature sensing means for sensing the skin temperature of said infant, the output of which is supplied to said control means.

Preferably said cover means is a substantially transparent hood.

Preferably said cover means includes means for obscuring said cover means.

Preferably said means for obscuring comprises a Liquid chyrstal panel integrally formed with said hood.

Preferably said cover means includes a first access means for partial access to said infant.

Preferably said cover means is generally hemispheric in geometry and may be adjusted from a closed position in which it substantially seals against said surface and an open position for full access to said infant.

Preferably in said open position said cover means is stored underneath said surface.

Preferably said at least one radiant heating means comprises an upper radiant element associated with said cover means and a lower radiant element associated with said support surface.

Preferably said upper radiant element is configured about said cover means such that the radiant heat energy incident on said infant is approximately evenly distributed over the length thereof.

Preferably said upper radiant element comprises a resistive ink printed on said cover means.

Preferably said support surface includes an air filled mattress being transparent to infra-red wave length radiant energy, and said lower radiant element being located underneath said mattress.

Preferably said lower radiant element comprises:

a housing means including a contact surface for contacting the underside of said mattress,

one or more radiant heating elements disposed within the bulk of said housing means in a location spaced from said contact surface and,

an infrared radiation barrier means blocking infrared radiation from said elements in directions away from said contact surface; said housing means incorporating infrared transmission means between said elements and at least adjacent regions of said contact surface, and said adjacent regions of said contact surface being infrared transmissible also.

Preferably said temperature sensing means are disposed on the upper surface of said mattress which in use contact with the skin of said infant and measuring the skin temperature thereof.

In a second aspect the present invention may be broadly said to consist in a mattress adapted for use in a neonatal incubator comprising:

a flexible support structure being transparent to infra-red wave length radiant energy, and

a radiant element being located underneath said flexible support structure including: a housing means having a contact surface for contacting the underside of said flexible support structure; one or more radiant heating elements disposed within the bulk of said housing means in a location spaced from said contact surface; and an infrared radiation barrier means blocking infrared radiation from said elements in directions away from said contact surface; said housing means incorporating infrared transmission means between said elements and at least adjacent regions of said contact surface, and said adjacent regions of said contact surface being infrared transmissible also.

Preferably said flexible support structure comprises an air filled cushion.

Preferably said air filled mattress is constructed from clear PVC.

Alternatively said air filled mattress is constructed from clear Polythene.

In a third aspect the present invention may be broadly said to consist in an apparatus for heating an infant comprising:

a surface adapted to support said infant,

cover means adapted to attach to and extend over said surface, and

at least one radiant heating means associated with either said cover means or said surface, and

a support structure adapted to automatically raise or lower said surface.

Preferably said support structure including a gas lift mechanism and a user interface means, whereby said interface means controls said gas lift mechanism to raise or lower said support structure as desired.

Alternatively said support structure including a electromechanical actuator and a user interface means, whereby said interface means controls said electromechanical actuator to raise or lower said support structure as desired.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1, is a perspective view of the incubator according to the preferred embodiment of the present invention in a closed state,

Figure 2, is a cross-section of the incubator according to the preferred embodiment of the present invention

Figure 3 is a cross section similar to Figure 2, showing the incubator cover in more detail,

Figure 4 is a perspective view of the incubator according to an alternative embodiment of the present invention in an open state,

Figure 5 is a perspective view of the lower radiant element according to the present invention, and

Figure 6 is a cross section through AUTHORISATION OF AGENT of the lower radiant element of Figure 5.

The present invention provides an efficient system for caring for infants required to be treated in an incubator by providing a thermo-neutral environment. Effectively, a radiant element integrated with the incubator cover, radiates heat energy to the infant at a level which approximately balances with the energy emitted or lost by the infant. Since the environment within the incubator is closed and controlled, ie: minimal conduction or convection losses, the baby's net heat loss will approximately zero. This means that the infant will be able to regulate its temperature effectively without intervention.

Incubator Construction

Referring now to Figure 1, we see a general perspective view of the incubator 100. The incubator 100 is supported by a column 102 which may be adjusted in height using either automatic electromechanical means or a gas lift system similar to that used in office chairs. At its base 104 the support column 102 includes preferably lockable castor wheels 108 to allow the incubator 100 to be portable and moved around the hospital environment.

The incubator 100 itself is comprised of a transparent cover 120 and a body portion 122 on which the infant is supported. In one embodiment of the present invention, the overall shape of the incubator is substantially oval or egg-shaped. However, it will be appreciated that any general geometry will be similarly suitable. The upper radiant heater element (shown in more detail in Figure 3) is integrated with the underside of the cover 120 which is configured such that the radiant heat generated thereby is directed substantially at the infant.

As well as being radiated by the upper radiant element 122, the infant will also be radiantly heated underneath by way of the heated mattress 130 on which the infant will lie as shown in Figure 2. The mattress 130 itself in one embodiment of the present invention may comprise an air-filled cushion similar to other air-filled mattresses. A lower radiant heater element 132 (which will be described later) is positioned directly

underneath the mattress 130. The lower radiant element 132 radiates energy using a wavelength in the Infra-red band through the mattress and directed at the infant. In order to achieve this, the mattress 130 must be constructed of a material suitable to transmit infra-red radiation. Clear heat resistant PVC or polythene might be suitable for this purpose.

A temperature sensor 140 is also provided on the upper surface of the mattress 130 in order to detect the skin temperature of the infant. As will be detailed later, this is used in the control of the radiant elements and also for safety purposes.

Cover Construction

Referring now to Figure 3, in which the incubator cover 200 is seen in more detail. The cover is designed such that in a closed position it will lock down on to the body portion and seal thereon. In this case it will provide an enclosed environment for the infant, as is required of commercial incubators.

The radiant heater element 202 integrated with the cover may take any one of a number of forms. In the preferred embodiment of the present invention a resistive ink is printed onto the inside surface of the cover similar to that used in the rear windscreen of cars. Each strip of resistive ink will be designed to be as thin and wide as possible in order to ensure the most efficient radiation distribution. Further, a radiation reflector may be provided behind each strip to ensure that all radiation is directed downwards towards the infant and not lost into the surroundings. The pattern printed on the cover is designed to ensure that there is an even temperature distribution across the entire length of the infant. Thus, in the central section farthest from the infant, the pattern will be more dense and at the outer reaches where the element will be closer to the infant the pattern is more sparse. The resistive ink is connected to a low voltage power source through connection 206, the power source being controlled by the incubator controller (described later).

For access to the infant, two levels of accessibility are provided. Firstly, an access hatch 204 is provided in the cover 200 which might slide across or, alternatively, swing open. This might be useful for example for hand access, of a nurse, to reattach vital sign sensors or other superficial tasks. In this case the radiant element on the cover heats the baby. In order to get full access to the infant, the entire cover 200 may be slid back to completely uncover the infant. The cover itself may slide into a holding cavity inside the body portion, or alternatively it may swing open. In this case a separate radiant heater either positioned over the baby or under the baby will provide heat.

In an alternative embodiment, full access may be provided by two halves of the cover sliding or swinging away, leaving a central portion in place. This central portion 300 shown in Figure 4 will be provided such that while the infant is being attended to, it will still obtain the benefit of some heating.

It will be appreciated that in most situations it will be of advantage to provide a darkened environment for the infant. To this end, the cover may be provided with a Liquid chyrstal panel in either a section or the entire cover. Such a panel allows control over whether light is blocked or transmit through the cover. Such panels are readily commercially available and work on the principle of variable polarisation depending on the electrical field applied.

Incubator Controller

Both the radiant element in the cover and the heater pad underneath the mattress are optimally controlled in order to provide a thermoneutral environment for the infant. The skin temperature of the infant is monitored in order to ensure that radiant heat energy being supplied to the infant approximates that of the total heat losses of the infant. Also, when the cover is removed and the infant is only heated by the mattress heater pad and/or a separate radiant heater the controller also ensures that as much heat energy is supplied to the infant as possible from the mattress heater pad without any adverse effects to the infant. The result is that the present invention provides a radiant infant incubator which efficiently provides a thermoneutral environment such that the infant may effectively regulate its own temperature without intervention both with the cover closed and with the cover off.

With the cover closed the elements are controlled to result in a infant skin temperature of approximately 37°C. With the cover open the mattress heater pad is controlled such that the infant skin temperature will also be approximately 37°C.

In such circumstances, it might also be desirable to have the air surrounding the infant to be humidified. The present invention provides added advantage in this circumstance since the provision of the radiant element in the cover will prevent condensation occurring thereon and the subsequent problems. If humidification means are to be provided then the interface would most likely also provide control over both the level of humidification and the temperature of the incubator environment. The air within the incubator might also be pressurised and would come from a filtered clean air source.

Lower radiant heater element

Referring to Figures 5 and 6, the preferred embodiment of the lower radiant heater element according to the present invention comprises a flexible warming pad 401. The warming pad 401 has a main, flexible, body 402. The body 402 includes a raised periphery formed by sides 403 together with ends 405. Within this periphery are located a series of parallel channels 406. Within each channel 406 is located a radiant heating element 408. The radiant heating elements 8 are connected in parallel by a pair of power supply wires 412, 413 which extend from the pad 401 for connection to a power source. An infrared transparent cover 409, not shown in Figure 5, encloses the space within the periphery of the main body 402, spanning between the tops 422 of the walls 404 left by the channels 406. Alternatively the cover 409 may only be partially transparent to infrared, the remaining heat energy being transferred through conduction to the infant.

The main body 402 is preferably formed from a soft and flexible material such as a suitable elastomeric material. An example of a suitable material is silicon rubber such as that manufactured and supplied by Dow Corning or thermoplastic polyurethane by Bayer.

With a material such as the Dow Corning silicone rubber, protection is necessary from the local application of radiant energy by the heater elements. An infrared radiation barrier is preferably provided. This infrared radiation barrier may for example comprise a metal foil or woven glass fibre barrier or a deposited ceramic coating such as a mica coating. The infrared radiation barrier is preferably substantially reflective or scatterative of infrared radiation around the chosen wave length and may be silvered or plated with a reflective material to achieve this effect.

The channels 406 in the main body 402 are preferably shaped having a curved, for example, substantially parabolic, profile such that radiation reflected by the infrared barrier is substantially evenly distributed upon exiting the channels.

The heater wires 408 preferably lay along the bottom of each channel 406 and are secured in place, for example, by zig zag stitching 410 through the gel main body 402. Electrical supply to the resistive wires 8 is typically at a low voltage (eg 8v) and consequently a metallic thread of low conductivity can be used for the zig zag stitching 410 without significant power conduction thereby. As one possible alternative ceramic beads formed around the wire and bonded to or moulded into the elastomeric material may support each wire.

The resistive wires 408 are connected in parallel (or parallel series combination) by the supply wires 412, 413. The supply wires 412, 413 are preferably of a substantially lower resistance material, for example, copper and given the high load that they will carry are of preferably a larger gauge than the resistive wires 408. The supply wires 412, 413 preferably extend the length of the pad 402 passing through each of the walls 404 separating the channels 406. The resistive wires 8 are connected to the supply wires 412, 413 at non insulated positions 14 there along. The wires 412, 413 are preferably provided exiting the pad 402 at a single convenient location and consequently are required to traverse the width of the pad 402 this traverse may occur within the final channel 416 (see Figure 6), for example such as indicated by traversing section 417 of conductive supply wire 412.

The radiant heating elements 408 are of comparatively high resistance and the material thereof is selected to provide infrared radiation in a frequency band which is readily absorbed over certain depth by human flesh or water. Radiation in the infrared A & B spectrums is appropriate in this case. Given that blood is substantially composed of water this ensures that radiation from the pad 401 is at least absorbed by the blood stream of the patient having been partially transmitted through the skin of the patient without significant heating of the skin. Radiation absorbed by the skin is absorbed over the full depth of penetration allowing significantly greater total heat input per unit volume than is achievable by conductive or convective heating, where all heat must pass through at least the outer layer, for the same effect on skin temperature. An example of suitable wire is Nickel Chromium eg: 80/20 or 60/40 and typically of a gauge of 24 B&S, 40 B&S 25SWG or 44SWG.

The infrared transparent film 409 is preferably secured to the gel main body 402 along the top 422 of each wall 404 between channels 406. This connection may for example be by an adhesive such as contact glue, or over moulded or welded. The cover 409 may for example comprise an infrared transparent film such as a polyethylene based film.

It will be appreciated that what has been described above is an improved neonatal incubator, with a number of advantages over the prior art. Firstly it uses radiant elements to heat the infant, as opposed to other ineffective and inefficient methods such as convection or conduction. Secondly it is controlled to counterbalance radiant heat losses of the infant.

Thirdly it allows unimpeded access to the infant, whilst still heating the infant. This is of significant advantage, as some treatment may extend for a significant period - where otherwise the baby would cool with the subsequent ill effects. Lastly the babies environment can be controlled with regard to light intensity.

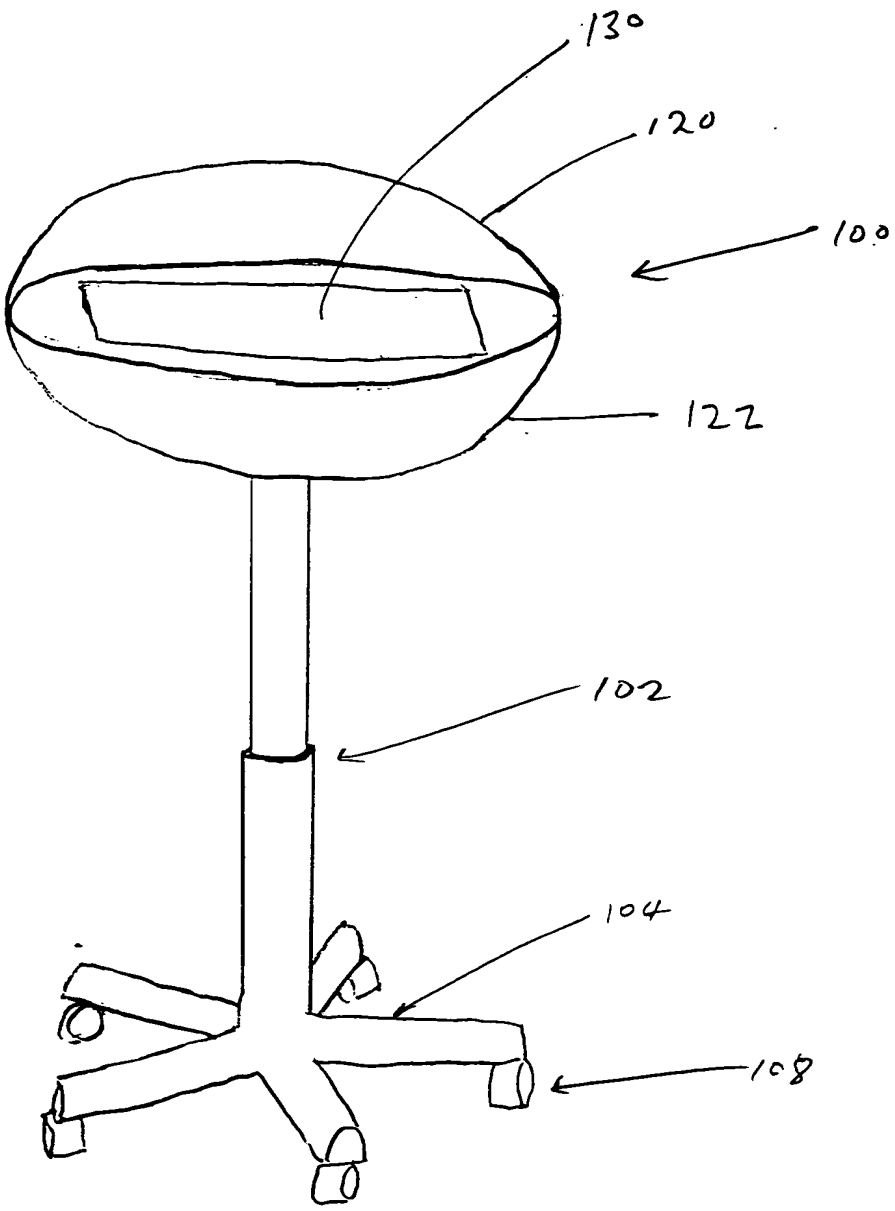

FIG. 1

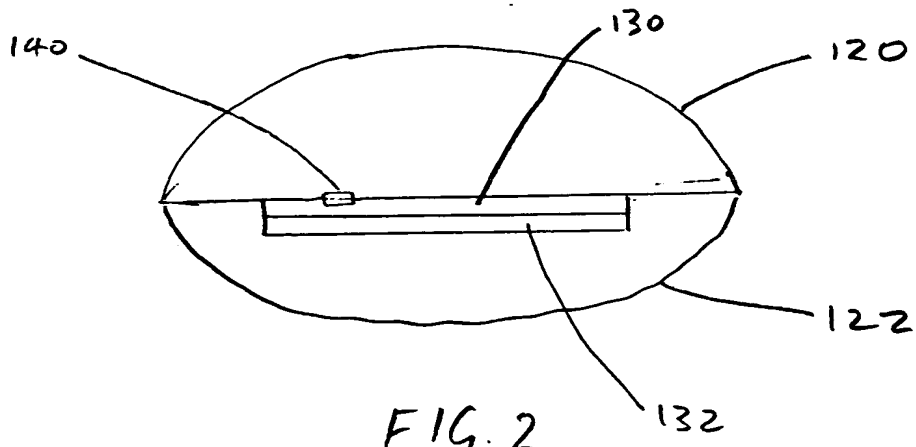

FIG. 2

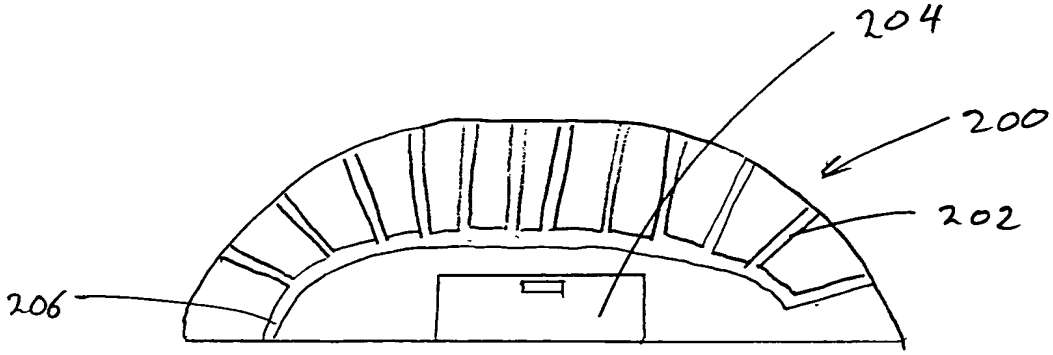

FIG. 3

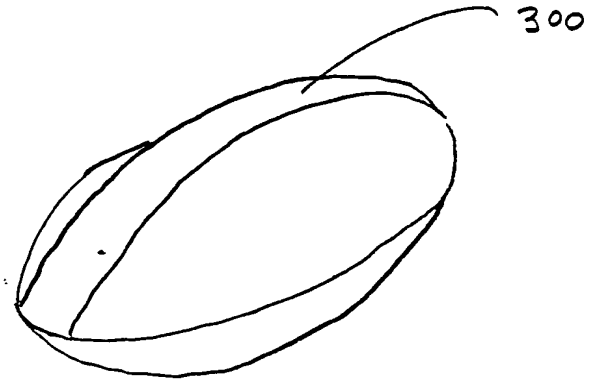

FIG. 4

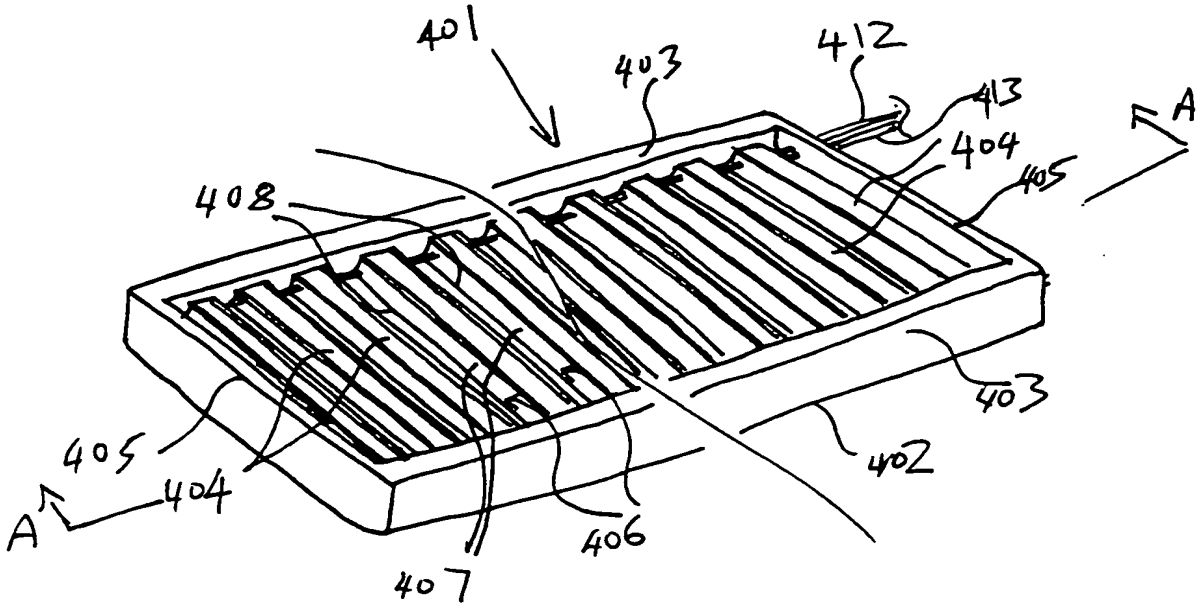

FIGURE 5

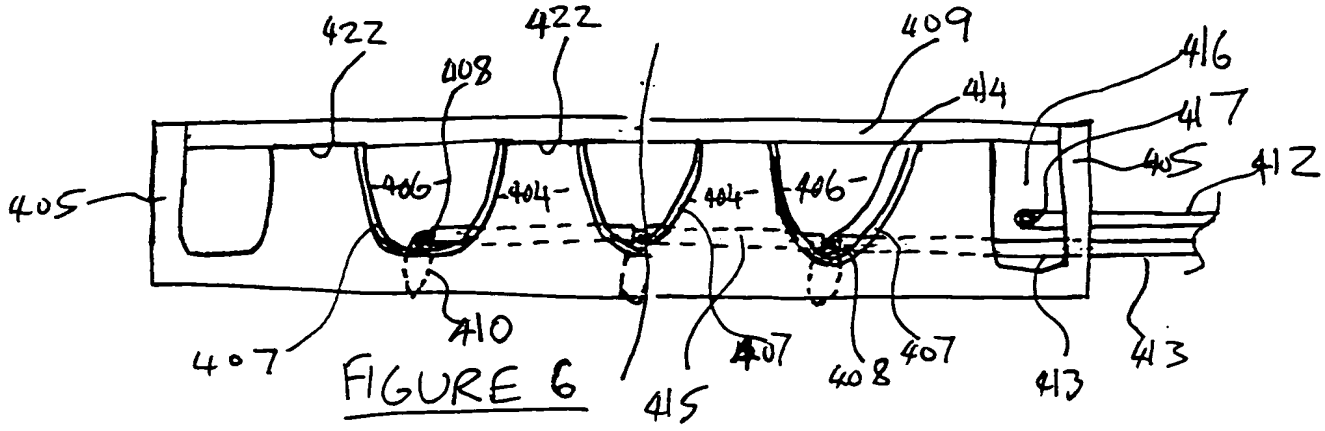

FIGURE 6